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10/582,422	06/09/2006	Hoi-Ying N. Holman	LBNL-238 (IB-1867-US)	4848
24972 7590 12/01/2009 FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			EXAMINER BRUTUS, JOEL F	
			ART UNIT	PAPER NUMBER
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			12/01/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/582,422

**Applicant(s)**

HOLMAN, HOI-YING N.

**Examiner**

JOEL F. BRUTUS

**Art Unit**

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/10/2009</u>   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 29-40 and 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al (US Pat: 5,293,872) stand alone AND/or in view of Dukor et al (Pub. No.: US 2002/0164810).

Regarding claims 29, 34, and 42-43 and 50, Alfano et al teach a system for in vivo or in vitro testing of a cardiovascular tissue sample to determine if the tissue is calcified atherosclerotic, fibrous atherosclerotic or normal [see column 8 lines 15-18] that is pertinent to the claimed invention [see abstract]. Alfano et al teach an endoscope 141 (which is used as a catheter, emphasis added) which is sized and shaped to fit within an artery or other blood vessel; an optical fiber bundle 147, which is used to illuminate the interior of the artery for imaging on a monitor as in FIG. 8 [see column 9 lines 8-28].

A fiber optic bundle 149 that is used to convey infrared light and fluorescence-inducing light (e.g. ultraviolet light, visible light) to the arterial tissue and to collect the resulting Raman scattered light for use in detecting calcified atherosclerotic tissue and the resulting fluorescence for use in detecting fibrous atherosclerotic tissue or normal tissue respectively [see column 9 lines 8-28].

Alfano et al disclose a system 51 includes a laser 53 for producing a beam 55 of monochromatic infrared light. The beam is reflected off a mirror 57 and passes through a lens coupler 59 into an input leg 60 of a bifurcated optical fiber bundle assembly 61 disposed within a probe, which is in the form of an endoscope 63 [see fig 10]. The light strikes the tissue T being tested and produces Raman scattering. The scattered light is then transmitted back through an output leg 62 of assembly 61 to a Michelson interferometer 65 [see column 6 lines 39-50 and column 7 lines 1-15]

Alfano et al teach an electronic signal preprocessing unit 69, which interfaces detector 67 to a computer 71. The output of computer 71 is then sent either to a plotter 73, which plots the Raman spectrum, or to a ratiometer 75, which calculates the ratio of intensities at two common characteristic Raman lines, such as the Raman bands at a Raman shift of about 1453 and 1659  $\text{cm}^{-1}$  in the case of human aortic tissue [see column 6 lines 39-50 and column 7 lines 1-15]. Alfano et al teach using wavenumbers 1659  $\text{cm}^{-1}$  and 957  $\text{cm}^{-1}$  which fall in the range of 4000  $\text{cm}^{-1}$  to 400  $\text{cm}^{-1}$  [see column 8 lines 1-14 and see figs 2-4].

Alfano et al further teach that the output from ratiometer 75 is then sent either to a display 77 or to a computer analyzer 79, which compares the intensity ratio for the tissue being tested with standard ratios from calcified atherosclerotic tissue and from fibrous atherosclerotic tissue or normal tissue [see column 6 lines 39-50 and column 7 lines 1-15]. The computer analyzer is used as the comparator to compare selected wavenumbers with absorbance peak with a normal to determine whether a tissue and/or

blood vessel is atherosclerotic and data/spectra from normal tissue as considered or used as reference data/spectra (emphasis added).

Alfano et al don't refer to selected wavenumbers as mid-IR in their description.

However, as in claims 42-43 mid-IR range between  $4000\text{ cm}^{-1}$  to about  $400\text{ cm}^{-1}$ ; Alfano et al teach using wavenumbers  $1659\text{ cm}^{-1}$  and  $957\text{ cm}^{-1}$  which fall in the range of  $4000\text{ cm}^{-1}$  to  $400\text{ cm}^{-1}$  [see column 8 lines 1-14 and see figs 2-4].

However, Dukor et al teach mid-IR absorbance spectra around  $1280\text{ cm}^{-1}$  [see figs 2-3, 0015-0016, 0024]; a device can be used to diagnosed for malignancy; inflammatory processes [see 0033]. Wavenumber around  $1280\text{ cm}^{-1}$  is effective for pathology detection [see 0009]. Dukor et al also teaches a computer with a software application for IR imaging data collection and spectroscopy analysis [see 0060];

Therefore, one with ordinary skill in the art would be motivated to combine Alfano et al and Dukor et al mid-IR wavenumbers around  $1280\text{ cm}^{-1}$  is effective for pathology detection [see 0009, Dukor et al]. Inflammatory processes and degenerative conditions [see 0033]; extracellular material such as blood, plasma, saliva, secretions, urine and sweat imply determining a chemical composition (emphasis added). One would have been motivated to determine a chemical composition and cellular condition; for the purpose of having an accurate and reliable diagnosis.

Regarding claims 30-33, 35-36, all other limitations are taught asset forth by the above teaching.

Alfano et al teach absorbance peaks of wavenumbers  $1659\text{ cm}^{-1}$  and  $957\text{ cm}^{-1}$  and range of  $700\text{ cm}^{-1}$  to  $1900\text{ cm}^{-1}$  [see column 8 lines 1-14 and see figs 2-4] which fall in the range of  $4000\text{ cm}^{-1}$  to  $400\text{ cm}^{-1}$ ;  $1690\text{--}1610\text{ cm}^{-1}$ .

With regards to resolved map; Alfano et al teach a map of generated spectral signals from different locations within a blood vessel [see fig 4].

Regarding claim 37, all other limitations are taught as set forth by the above teaching. Alfano et al further teach an interferometer [see column 6 lines 39-50 and column 7 lines 1-15].

Regarding claims 38 and 44, all other limitations are taught as set forth by the above teaching. Alfano et al further teach that the endoscope includes a cuff 143 surrounds all but the tip of a cable 145 [see fig 10], which includes four channels; cable 145 has a tip or tip array [see fig 10]. Alfano et al also teach an optical fiber bundle 147 (used as a source fiber, emphasis added); a fiber optic bundle 149 (used as a detector, emphasis added) for use in detecting calcified atherosclerotic tissue, fibrous atherosclerotic tissue or normal tissue [see column 9 lines 8-28].

With regards to the fiber optic cable of claim 44, Alfano et al disclose a cable 145 in fig 10 that includes four channels at its tip [see fig 10]. Alfano et al also teach that cable 80 is similar in construction with fiber optic bundle 149 [see column 9 lines 16-17]. Therefore, cable 80 has to be a fiber optic cable (emphasis added).

Regarding claim 47, all other limitations are taught as set forth by the above teaching. Alfano et al teach a spectrophotometer [see column 5 lines 26-27].

Regarding claim 40, all other limitations are taught as set forth by the above teaching.

Alfano et al teach a liquid nitrogen cooled indium gallium arsenide photodiode type detector [see column 5 lines 21-23].

Regarding claims 45-46, and 48-49, all other limitations are taught as set forth by the above teaching.

Alfano et al further teach the endoscope which includes the cable would be used as the catheter means for insertion in body lumens (emphasis added). Alfano et al teach spectrum analyzer, fluorescence analyzer, and endoscope probing cable [see fig 9]. The fiber cable transmits reflected light to the spectrum analyzer for performing spectroscopic analysis (emphasis added).

Alfano et al don't explicitly mention whether the optical cable 145 is rotatable within the body lumen.

However, it is well known in the art that catheters and endoscope are rotatable within a body lumen such as a blood vessel (emphasis added).

Therefore, it is inherent that cable 145 within the endoscope rotates radially within the blood vessel to acquire data at various locations; thus performing 360 degrees spectral analysis (emphasis added).

Regarding claim 39, all other limitations are taught as set forth by the above teaching.

Alfano et al don't teach a tuning system.

However, Dukor et al teach an acousto-optical tunable filter or liquid crystal tunable filter could be used to switch back and forth between the wavelengths of the two baselines points to obtain slope measurement [see 0063].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Alfano et al and Dukor et al reference; for the purpose of using a desired wavenumber.

3. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al (US Pat: 5,293,872 in view of Dukor et al (Pub. No.: US 2002/0164810) as applied to claim 34 above and further in view of Corenman et al (US Pat: 4,817,013).

Regarding claim 41, all other limitations are taught as set forth by the above combination.

Alfano et al don't teach customized bandwidth and special gain for DC or AC preamps.

However, Corenman et al teaches preamp [see 6C]; fig 4A shows AC/DC separation circuit in the amplifiers that receive signal output from three infrared detectors.



Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Alfano et al and Corenman et al references; for the purpose of providing a more efficient system by improving its performance.

### ***Response to Arguments***

4. Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./  
Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768